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EXAMINER

VANDERVEGT, FRANCOIS P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840,243

Applicant(s)

MASTERNAK ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1,3 and 62 is/are allowed.
- 6) ☒ Claim(s) 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 09082003. 6) ☐ Other: _____

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DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a continuation of U.S. Application Serial Number PCT/EP99/08026.

Priority

1. Acknowledgment is again made of applicant's claim for foreign priority based on an application filed in Europe on 10/24/1998. It is noted, however, that applicant has still not filed a certified copy of the European application as required by 35 U.S.C. 119(b). Applicant's intent to file said certified copy, as asserted at page 8, section 5, of the remarks filed September 8, 2003 is acknowledged. However, until said submission is perfected, the objection stands.

Claims 4-61 and 63-76 have been canceled.

Claims 1-3 and 62 are currently pending and are the subject of examination in the present Office Action.

Request for Information - 37 CFR § 1.105

2. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

Applicant's filing of a declaration under 37 CFR § 1.131 on September 8, 2003 over the signature of all inventors is acknowledged. In the declaration Applicant avers, in section 5 of the declaration and as evidenced by Exhibit 5 attached thereto, that the submission of the claimed human RFXANX protein sequence of SEQ ID NO: 11 to NCBI's Entrez protein database took place on September 25, 1998. Accordingly, the date of submission is more than one year prior to the October 24, 1999 filing date of the PCT/EP99/08026 priority application. Said sequence was published in the journal Nature Genetics in November 1998 as evidenced by Exhibit 2 of the declaration. It is not clear, however, on what date the sequence was made publicly available by NCBI, i.e., was the sequence made public on September 25, 1998 (the date of submission), on the date of publication in November 1998 or on some date in between.

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If the sequence was made publicly available through NCBI prior to October 24, 1998, claims 1-3 and 62 may be subject to rejection under 35 USC § 102(b) over the NCBI disclosure.

Therefore, in accordance with 37 CFR 1.105, Applicant is required to provide information demonstrating the date of public availability of the sequence through NCBI's Entrez protein database.

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

In view of Applicant's amendment filed September 8, 2003, only the following ground of rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 2 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It was previously stated: "It is apparent that the cell lines BLS1, Na and [Ab] are required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of said cell lines. *See 37 C.F.R. 1.802.*

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. *See 37 C.F.R. 1.808.*

In addition, the identifying information set forth in 37 C.F.R. 1.809 (d) should be added to the specification. *See 37 C.F.R. 1.803-1.809* for additional explanation of these requirements, Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required (ATCC, 10801 University Boulevard, Manassas, VA 20110-2209).

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the plasmid described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from Applicant to the depository coupled with

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corroboration that the deposit is identical to the biological material described in the specification and in the Applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 C.F.R. 1.801-1.809 for further information concerning deposit practice.”

Applicant has traversed the ground of rejection, asserting that the cell lines are exemplary only and not required for practice of the claimed invention and that the cell lines were publicly available. In regard to Applicant's first assertion, this is not convincing because recitation of the cell lines in the claim require that the isolated protein or peptide is from a cell of the recited cell lines, accordingly requiring that a cell of the recited cell lines be in possession of the artisan for practice of the invention within the metes and bounds of that claim. Applicant's second assertion showing that the cell lines were present in published reports prior to the filing date of the instant application is acknowledged. However, in order to adequately demonstrate the asserted public availability of the cell lines, there should be a showing that 1) the cell line is commercially available, 2) a showing in at least one of the publications that the author would provide the cell lines upon request and without restriction or 3) demonstration that it was a policy of the journal in which the report was published at the time of publication that all cell lines in the reports would be provided by the author upon request and without restriction. Applicant is cautioned that claim 2 must also be amended to recite the commercial or depository names of the cell lines rather than just their laboratory designations, otherwise the claim would be deemed indefinite.

Information Disclosure Statement

3. All references on the form PTO-1449 filed September 8, 2003 have been lined through as duplicate citations, as they have all been indicated as considered in the initialed and signed form PTO-1449 attached to the Office Action mailed March 25, 2003.

Conclusion

4. Claims 1, 3 and 62 are allowed, subject to a showing that the protein sequence of SEQ ID NO: 11 was not made publicly available prior to October 24, 1998.

5. This Office action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

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6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

As of January 7, 2004, the Examiner's telephone number will be (571) 272-0852.

F. Pierre VanderVegt, Ph.D. *RV*
Patent Examiner
December 11, 2003

Patrick J. Nolan
PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
12/12/03